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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,282

08/21/2006

Danuta Ciok

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EXAMINER

KIDWELL, MICHELE M

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

12/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,282	<b>Applicant(s)</b> CIOK ET AL.	
	<b>Examiner</b> Michele Kidwell	<b>Art Unit</b> 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3,6-8,11,12,15 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,9,10,13,14 and 16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Species I in the reply filed on August 18, 2008 is acknowledged. The traversal is on the ground(s) that all of the figures may include any and/or all of the elements shown in all figures. This is not found persuasive because the specification states that the corresponding figures are different embodiments and the elements are provided separately (col. 7, line 31), and therefore are not mandatory in each embodiment. The applicant states that there is no substitution of elements; however, none is required for the distinction of embodiments. The examiner also notes that while a stiffening element is shown in figure 1, a stiffening element including notches is depicted in figures 4, 5a and 5b – a non-elected embodiment. Accordingly, claims directed to a stiffening element with notches are considered non-elected.

The requirement is still deemed proper and is therefore made FINAL.

Claims 3, 6 – 8, 15 and 17 – 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 8, 2008.

With respect to the statement that no claims are generic, the examiner has reconsidered and agrees that claims 1 and 13 are generic.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the protecting layer must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 – 2 and 13 – 14 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Leise, Jr. (US 5,401,264).

With respect to claims 1 – 2 and 13 – 14, Leise, Jr. (hereinafter “Leise”) discloses an ostomy appliance comprising a front wall and a rear wall of flexible material forming a bag, said rear wall having an opening for receiving a stoma (figure 1), and being provided with an adhesive wafer (col. 2, line 67 to col. 3, line 3) for securing the appliance to a user's skin, said wafer having a hole being aligned with the opening for receiving the stoma (figure 1), wherein the opening of the rear wall has an edge being adapted to be secured to a surface of the adhesive wafer facing away from the user in an attachment zone surrounding the hole of the wafer as set forth in col. 3, lines 3 – 7. Leise discloses that the attachment of the wafer to the edge of the rear wall may include a heat seal (permanent) or adhesive. In either case, the both first and second parts of the edge of opening may be considered to be prepared for adhesive sealing to remaining parts of an attachment zone.

Alternatively, one of ordinary skill in the art to employ both types of seals in order to provide the benefits associated with a one-piece and two-piece ostomy device which is well known in the art as evidenced by Leise in col. 3, lines 8 – 12.

Claims 1 – 2, 4 – 5, 9 – 10, 13 – 14 and 16 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Thomas (US 4,865,594).

With respect to claims 1 – 2 and 13 – 14, Thomas discloses an ostomy appliance comprising a front wall and a rear wall of flexible material forming a bag, said rear wall having an opening for receiving a stoma (figure 2), and being provided with an adhesive wafer (col. 3, lines 18 – 21) for securing the appliance to a user's skin, said wafer having a hole being aligned with the opening for receiving the stoma (figure 2), wherein the opening of the rear wall has an edge being adapted to be secured to a surface of the adhesive wafer facing away from the user in an attachment zone surrounding the hole of the wafer as set forth in col. 3, lines 16 – 28. Thomas discloses that the attachment of the wafer to the edge of the rear wall may include a heat seal (permanent) or adhesive in col. 3, lines 18 – 21. In either case, the both first and second parts of the edge of opening may be considered to be prepared for adhesive sealing to remaining parts of an attachment zone.

Alternatively, one of ordinary skill in the art to employ both types of seals in order to provide the benefits associated with a one-piece and two-piece ostomy device which are considered “common joining procedures” as taught by Thomas in col. 3, lines 18 – 21.

With reference to claims 4 – 5 and 16, Thomas provides the ostomy appliance with a stiffening element to which first and second parts of the bag are secured as set forth in col. 3, lines 23 – 25.

Regarding claims 9 and 10, Thomas provides a protecting layer as set forth in col. 3, lines 29 – 41.

***Response to Arguments***

Applicant's arguments with respect to claims 1 – 20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Kidwell whose telephone number is 571-272-4935. The examiner can normally be reached on Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Michele Kidwell/  
Primary Examiner, Art Unit 3761